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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/271,024

03/17/1999

ASGEIR SAEBO

CONLINCO-036

3480

23535 7590 08/13/2002

MEDLEN & CARROLL, LLP
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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/271,024	SAEBO ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Request for a Continued Examination (RCE), filed on May 10, 2002, under 37 CFR 1.114 based on parent Application No. 09/271024 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 13 recites "said composition characterized..." in line 6. However, there are two different "composition" recited in the claim: "composition" recited in line 1 and composition recited in line 2. Therefore, it is unclear the "said composition" is referred to which composition. The claims are indefinite as to the amounts of c9, t11 octadecadienoic acid, and t10, c12 octadecadienoic acid in the composition.

Claim Rejections 35 U.S.C. 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 5-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Cain et al. (WO 97/18320, IDS).

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5. Cain teaches an acyglycerol composition comprising mono- di- and tri-glyceride wherein the fatty acid are c9,t11 CLA or t10, c12 CLA, wherein the total CLA in the composition is about 63.8%, of which 48.9% was the cis 9, trans 11 isomer and 51.1 % was the trans 10, cis 12 isomer. No other CLA isomers are indicated, or suggested to be present in the composition.

Claim Rejections 35 U.S.C. – 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cain et al. (WO 97/18320, IDS).

Cain teaches an acyglycerol composition comprising mono- di- and tri-glyceride wherein the fatty acids are c9,t11 CLA or t10, c12 CLA, no other isomer was employed for the esterification forming the acyglycerol composition. See, example 6-10 at page 16-22.

Particularly, Cain et al. have characterized all the fatty acid through gas chromatography and have identified the CLA. For example, in example 6, it state “The fatty acid composition of the product, as determined by FAME GC, contained 63.8% CLA, of which 48.9% was the cis 9, trans 11 isomer and 51.1 % was the trans 10, cis 12 isomer.” See page 16, lines 17-21. it is suggest that the rest of the fatty acids are not CLA, and the CLA is composed entirely of cis 9, trans 11 isomer and trans 10, cis 12 isomer. (48.9% + 51.1 % = 100%). The composition may be

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used in various food products including ice cream, soup, and bakery products. See, particularly, examples 12-17 at page 24-35 and the claims.

The reference do not teaches expressly that each of the isomers must be 30% or more of the total CLA moieties for the particular food products. However, it would be obvious to employ such CLA composition in the food product, since such CLA composition has been expressly disclosed by Cain. See, the example 6.

Claims 5-8 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen et al. (US 5,885,594) in view of Cain et al. (WO 97/18320, IDS), further in view of Pariza et al. (U.S. Patent 5,017,614)

Nilsen et al teach a composition comprising 90-100 % of an acyglycerol compound wherein the fatty acid radical is a conjugated polyunsaturated fatty acid. See, particularly, column 3, lines 5-15. The preferred conjugated polyunsaturated fatty acid is conjugated linoleic acid which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid. See, particularly, column 3, lines 14-15 and column 4, lines 4-6. Nilsen et al. further teaches food product comprising the said composition. See, particularly, column 12, lines 30-67, column 13, lines 1-67 and column 14, lines 1-9.

Nilsen et al. do not teach expressly the employment of the combination of c9, t11-octadecadienoic acid and/or t10, c12-octadecadienoic acid in the acyglycerol, or the specific amounts of each of the two isomers, i.e., c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid, or the employment of the composition in animal feed.

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However, Cain et al. teach that both c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid are considered the active isomers of CLA, and are known to be beneficial for animal health, See, particularly, page 1, lines 8-25. Cain further teaches a method of making both c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid. See, particularly the examples.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the composition of Nilsen et al. with acyglycerol compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid and employ the composition in feed for animals. Note that Nilsen et al do not use the other isomers of conjugated linoleic acids specified herein. Therefore meet the limitation set forth in claim 5 that other isomers are present in amounts less than 1% is meet.

A person of ordinary skill in the art would have been motivated to make the composition of Nilsen et al. with acyglycerol compounds wherein the fatty acid moiety is a mixture of c9, t11-octadecadienoic acid and c10, t12-octadecadienoic acid only without employing other isomers and employ the composition in feed for animals because both isomers are known to be the active isomers and are useful in food or feed products. The optimization of the ratio of the compounds is considered within the skill of artisan. Further, a composition known to be useful in food products is reasonably expected to be useful in feed products for animal. Further, Pariza is cited to show that person of ordinary skill in the art possess the skill of preparing/or isolating the pure single isomer employed herein. See, particularly, column 4, line 50, bridging column 8, lines 68, wherein, the separation, purification, and analysis of the isomers are discussed.

Response to the Arguments

Applicants' arguments submitted May 10, 2002 have been fully considered, but are not persuasive. In view of the new ground rejection set forth above, only issues related to above rejection are discussed below.

Applicants' assertion that the examiner has overstated the cited references and the state of the art at the time of filing is in error. Particularly, applicants erred in citing Yurawecz reference as evidence that all the CLA composition prior to the time of the filing the application, including those disclosed in the cited prior art, containing more than 1% of unwanted isomers. Yurawecz reference contains no factual evidence showing the analyzed commercial samples would encompass the CLA compositions taught in the cited references, particularly, the one described in example 6 in Cain reference. In fact Yurawecz reference provides no indication, or a hint that the analyzed samples would relate to the teaching in the cited references. In establishing their arguments, applicants have made several assumptions without any factual supports: a) Yurawecz analyzed all commercial CLA composition; b) all the CLA compositions known in the art at the time of filing the present application have been commercialized; c) only commercialized, or commercializable CLA compositions read on the claimed composition. The finding that some of the commercial products containing other isomers would not necessarily lead to the conclusion that all the CLA compositions known in the art at the time of filing the present application contain the other isomers. Note the claimed composition read on composition in any scale, not only commercial composition.

Applicants have miscalculated the acyglycerol product in example 6, (page 8, second paragraph. Note examples 1-5 of Cain reference are drawn to method of isomerization of free

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linoleic acid and esterification of the free CLA. Example 6 is directed to isomerization of esters (sunflower oil), therefore, all the CLA are attached to glycerol. No issue of conversion.

Regarding the remarks of criticality about the less than 1% of the isomers herein, note the prior arts has teaches the usefulness of the c9, t11-octadecadienoic acid and c10, t12-octadecadienoic acid, any composition comprising these two isomers as the major ingredients would be prima facie obvious over the prior art. The instant invention relies on the limitation “less than 1%” of the other isomers as the point of novelty, without illustrating how this limitation make the claimed invention patentably distinct from the prior art. Lacking the criticality of such limitation, the claimed invention would be properly rejected over Nilsen et al. in view of Cain et al., further in view of Pariza et al.

Sugano reference would not be sufficient to overcome Cain reference since the conditions of the examples are different, e.g., the starting materials, and the scales are different.

Applicants’ assertion that many of the isomers have not been recognized in the art is improper. As shown by Pariza et al., or Chin et al., the analytical method for such isomers has long been developed. The assertion that Cain’s analytical results lack credit has no factual base.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

A handwritten signature in black ink, appearing to read 'S. Wang' with a stylized flourish at the end.

Shengjun Wang

August 10, 2002